Update on the Implementation of FDA's Establishment Registration and Product Listing Regulation

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Human Tissue Establishment Inspections Training

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Establishment Registration and Product Listing - When/Who?

- Final regulation published January 2001
- Effective April 4, 2001 for estimated
  - 90 tissue establishments - musculo-skeletal, skin
  - 110 eye establishments
- Effective January 2003 for estimated
  - 400 ART facilities/110 semen banks
  - 160 Hematopoietic stem cell establishments
  - Voluntary registration accepted now
- Probable that 1/2003 date will be extended

Exceptions for Registration- 1271.15

- Use HCT/Ps solely for nonclinical scientific or educational purposes
- Remove HCT/Ps from an individual and implant them into the same person during the same surgical procedure
- Carrier who accepts, receives, carries or delivers HCT/Ps (e.g. FedEx, UPS)

More Exceptions for Registration- 1271.15

- Only receive or store for use within your facility
- Only recover reproductive HCT/Ps for immediate transfer into the sexually intimate partner of the donor
- Individual who solely recovers HCT/Ps under contract or other agreement with registered firm

Establishment Registration and Product Listing - When 1271.21

- Initial registration by 4/4/01 or within 5 days after beginning operations
- Annual registration by 12/31/01
- Semi-annual update if add or discontinue a product
- An amendment is required within 5 days if ownership or location changes

Establishment Registration and Product Listing - How/Where 1271.22

- Form 3356 - mail or fax -indicated on form
  - Future web based submission being developed
- Current form is 9/01 version
- Less than 45 minutes to complete
- Q and A's (updated 5/2002) and form available at: www.fda.gov/cber/tissue/docs.htm

Initial Registration

- FDA/CBER receives form and enters data in the Human Cell and Tissue Establishment Registration (HCTERs) data base
- Copy of form is sent to FDA district office.
- District office will verify that the firm is in operation and is required to register
- District office generates and sends FEI registration number to CBER
- CBER sends validated Form 3356 to establishment and district office with the registration number

Annual Registration

- Establishments notified by CBER in November
- Establishments must return signed form by end of December
- If information changed – entered into HCTERS
- New form with new validation date sent to establishment and the district office

Reports to be Generated -1271.37

- Failure to register report - if more than 2 months late for the annual registration
  - Will be sent to district offices for follow-up
- Other reports are requested through CBER's Office of Communication, Training and Manufacturers Assistance (OCTMA)
  - Report information provided in the regulation
  - List of all registered establishments
  - List of all HCT/P's

Current HCTERS Database Status (5/02)

- 521 total establishments entered into the HCTERS database
- 447 establishments registered/ validated
- 58 pre-registered- awaiting assignment of FEI numbers by the district office
- 16 inactive
  - No longer involved with manufacturing HCT/Ps
  - No longer doing business

Current Active HCTERS Data (5/02)

- Required to registered - 419
- Not required to register - 86
- Total in database - 505
- Already registered as a device or blood establishment - 76
- Organ Procurement Organizations - 55
- Foreign establishments - 7

Listing of Registered Establishments

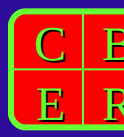
- List of establishments publicly available at (updated every 6 months) www.fda.gov/cber/tissue/hctregestabl.htm

Not Required to Register List

- Stem cells - 77
  - Peripheral blood
  - Umbilical cord blood
  - Bone marrow
- Reproductive -20
- Cellular therapies - 20
  - Dendritic, granulocytes, cytotoxic lymphocytes, tumor, mononuclear, kidney

Number of Establishments Listing Each Product

Bone	290	Oocyte	7	Umbilical Cord Blood Stem Cells	41
Cartilage	191	Pericardium	183	Vascular Graft	140
Cornea	138	Peripheral Blood Stem Cell	65	Amnion	7
Dura Mater	13	Sclera	115	Whole Eye	13
Embryo	6	Semen	19	Limbal Graft	14
Fascia	219	Skin	177	Tarsal Plate	14
Heart Valve	152	Somatic Cells	13		
Ligament	203	Tendon	219		



Number of Establishments Listing Each Function

• Recover	315
• Screen	289
• Test	155
• Package	210
• Process	233
• Store	373
• Label	242
• Distribute	338

Clarifications on Who Registers - Questions

- Blood bank stores purchased bone and ships to another institution for use
- Hospital stores tissue from a patient in case the surgeon needs it for another patient
- Satellite location across town where manufacturing is done
- Hospital gas sterilizes bone for further use

Clarifications on Who Registers - Questions

- Testing lab that performs donor testing for communicable diseases
- Organ procurement organizations that procure tissue or screen and/or test donors for registered establishments
- Foreign procurement sites that supply tissue for import to the US

Clarifications on Who Does Not Register - Questions

- Supplies tissues only for non-clinical research or educational use
- Building used only to store procurement kits-site under control of a registered facility
- Transfusion service stores tissue only for their own hospital's surgeries

Clarifications - Who Does Not Register - Questions

- Testing laboratory that only performs chemical or microbiological testing for donor tissue
- Sales individuals under contract to registered establishment and who don't distribute HCT/Ps
- Donor coordinators who are employees of a registered establishment that work out of their homes and who only recover

Who Registers in January 2003 or ?

- Establishments that only recover, screen, process etc. - heart valves or dura mater
- Hematopoietic stem cell establishments
- Semen banks, and IVF clinics
- Other cellular HCT/P establishments

District Tissue Registration Monitors

New England, Sylvia Craven

New York, Evelyn Taha

San Juan, Maridalia Torres

New Jersey, Rosa Brown

Baltimore, Gerald Mierle

Philadelphia, Robin Travers

Atlanta, Vincent Williams

Florida, Ronnie Jackson

Chicago, Linda Whitehead

Cincinnati, Marianne Allen

- Detroit, Catherine Quinlan
- International, Christine Twohy
- Dallas, Warren Landry
- New Orleans, Marion Ferrante
- Kansas City, Gregory Dixon
- Denver, Elvin Smith
- Los Angeles, Kirsten, Tharp
- San Francisco, Debra Kleinfeld
- Seattle, Dolores Price

Distribution of Establishments by FDA District Office

New England	20	Florida	42	New Orleans	3
New York	26	Chicago	13	Kansas City	2
San Juan	5	Cincinnati	27	Denver	2
New Jersey	16	Detroit	19	Los Angeles	4
Baltimore	27	Minneapolis	30	San Francisco	2
Philadelphia	17	Int. Operations Group	7	Seattle	2
Atlanta	36	Dallas	54		

Tissue Registration Contacts

- Tissue Registration Regulation Questions
  - Martha Wells – 301-827-6106 wells@cber.fda.gov
- Tissue Establishment Registration Coordinator
  - Vicky Carter - 301-827-6176 carterv@cber.fda.gov